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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,067	10/26/2001	Roger Coleman	PF-0069-1 CON	7844

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EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/033,067	Roger Coleman
Examiner	**Art Unit**
Prema Mertz	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 21, 2003*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3-7, 9, 10, 12-16, 28, 29, 46, 47, and 57-59* is/are pending in the application.

4a) Of the above, claim(s) *1, 14-16, 28, 29, 47, 58, and 59* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3-7, 9, 10, 12, 13, 46, and 57* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *10*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 2, 11, 17-27, 30-45, 48-56 have been canceled previously and claims 8 and 11 have been canceled in Paper No. 9, 1/21/03.

Election/Restriction

2. Applicant's election with traverse of Group II (claims 3-7, 9-10, 12-13, 46 and 57) in Paper No. 9 (1/21/03) is acknowledged. The traversal is on the ground(s) that the Examiner has made a restriction between Groups I and II and Applicants assert that no undue burden would be placed on the Examiner if the two Groups were to be considered in the same application as the searches would be co-extensive. This is not found persuasive because the searches for the two Groups would not overlap, the inventions being classified in different classes and subclasses. Applicants are directed to MPEP. 808.02 which states that "Where the related inventions as claimed are shown to be distinct and under the criteria of MPEP. 806.05 (c-I), the examiner in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: 1) Separate classification thereof." In the instant case, Group I is classified in class 530, subclass 351 and Group II is classified in class 435, subclass 69.5.

The test for propriety of restriction is not whether the inventions are related but rather whether they are distinct and whether it would impose a burden on the examiner to search and examine multiple inventions in a single invention. Since Group I and Group II are related as products which are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent

utility, that is distinct for each invention which cannot be exchanged. The polynucleotide of invention II can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of invention I can be used as a probe, or used therapeutically or diagnostically, e.g. in screening.

Therefore, contrary to Applicants arguments, a search of the polypeptide claims of the instant invention would not necessarily provide information regarding the polynucleotide claims which inventions are distinct because a search of the literature for the polypeptide, would not be expected to reveal art for the polynucleotide encoding the polypeptide, since the polypeptide could be obtained from natural sources without using the polynucleotide to produce the polypeptide which searches are extensive requiring separate searches which would be unduly burdensome.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

The Groups as delineated in the restriction requirement (Paper No. 8, 12/17/02) are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

Furthermore, Applicants request rejoinder of the subject matter of Groups II and methods of using the product of Group II (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995)), in which a new, unobvious material is used in a known process. Ochiai determined that a process was free of the prior art if it employed a product which was free of the prior art. However, only if the product claims of Group II are found allowable, the subject matter of Groups in which the product of Group II is used in a method will be rejoined with the product claims of Group II, if the process claims are of the same scope as the allowable product claims.

Claim 1 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 101/112, first paragraph

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-7, 9-10, 12-13, 46, 57 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant claims are drawn to a nucleic acid encoding a polypeptide which has an as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as having homology to hJE-2/MCP-2, MCP-3, MCP-1 (page 5, lines 27-31; Figure 2), the instant invention is incomplete. The translation product of the monocyte chemotactic proprotein (MCPP protein) encoded by the claimed polynucleotide, shares 64% sequence homology to MCP-1, 63% sequence homology to MCP-2/hJE and 62% to MCP-3 (see page 5, lines 29-35). However, the instant specification does not disclose any information regarding functional characteristics or the biological activity of the instantly claimed protein. While the specification on page 3, lines 11-20 describes many activities for the instant protein, such as to identify agonists, antagonists or inhibitors to modulate the activity of MCPP in allergic responses or autoimmune diseases, there is no guidance given about which specific activity/activities the polypeptide encoded by the claimed polynucleotide would be likely to have. The specification does not demonstrate that the MCPP polypeptide actually displays any of these recited activities. In the absence of knowledge of the specific biological significance of the claimed protein, there is no immediately obvious patentable use for it. Since the instant specification does not disclose a "real world" use for the nucleic acid

encoding the MCPP protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

A protein of unknown function would have utility if it can be employed as an indicator of a diseased state or of the presence of a disorder. The only disclosed function for the protein of the instant invention is that since expression of this gene family is often cell or tissue specific and associated with autoimmune, cancerous, inflammatory, infectious or hereditary conditions, the protein of the instant invention may be used to screen for receptors on the surface of leukocytes, cells of lymphoid or cancerous origin (see page 17, lines 35-39; page 18, lines 1-10). However, Applicants have failed to show that the instant protein is associated with any of the recited medical conditions. Applicant is only required to identify one substantial credible utility and the employment of this protein only as the subject of further research does not satisfy the utility requirement of 35 U.S.C. § 101 because the courts have interpreted this statute as requiring an invention to have "substantial utility" "where specific benefit exists in currently available form". The employment of a protein of the instant invention, as "bait" to fish for effective biological or organic pharmaceutical molecules is not a substantial or specific utility.

Applicants have asserted a possible clinical use of the polypeptide encoded by the claimed polynucleotide (pages 17-18) but have failed to provide results showing the use of or even a nexus between the instant polynucleotide encoding a chemokine and the recited disorders. There is no evidence of a co-relation between expression of the claimed protein and this recited disorder. Furthermore, the law requires that the invention be useful in currently available form. Applicants

do not disclose an association between the claimed polynucleotide encoding a protein and the recited disorder.

Applicants disclose in the specification that the claimed protein has homology to MCP-2/hJE-2 and MCP-3 (page 17, lines 35-37). The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Sklonick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Sklonick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, there is little doubt that, after further characterization, the protein is found to be member of this chemokine family, the claimed polynucleotide encoding a MCPP protein would have a specific, substantial and credible utility. However, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. The claimed invention is directed to a polynucleotide encoding a polypeptide of as yet undetermined function or biological significance. Thus, since there is no biological activity disclosed for the protein encoded by the claimed nucleic acid, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

Claims 3-7, 9-10, 12-13, 46, 57 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose a biological

activity for the claimed polynucleotide encoding a MCPP protein, therefore, there is no specific and substantial asserted utility or well established for the claimed polynucleotide. The fact that the claimed nucleic acid encodes a protein that has homology to MCP-2/hJE and MCP-3 protein is not sufficient to establish a specific and substantially asserted utility or a well established utility for it.

Should Applicants establish an activity for the polynucleotide encoding a polypeptide of SEQ ID NO:1, the instant specification would still fail to adequately describe and enable an isolated polynucleotide encoding a protein that is at least 90% identical to the polypeptide of SEQ ID NO:1. Applicants do not teach which regions of said polypeptide are critical to encode a functional polypeptide. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a polypeptide having at least 90% sequence identity to SEQ ID NO:1, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polypeptide, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

In summary, the amount of experimentation required for one of ordinary skill in the art to use the claimed invention, an isolated polynucleotide encoding a polypeptide that is at least 90% identical to the polypeptide of SEQ ID NO:1, would be undue. To practice the instant invention

in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those nucleotide sequences of the disclosed naturally-occurring nucleic acid encoding the MCPP polypeptide, which are required for functional and structural integrity of the MCPP polypeptide. It is this additional characterization of the disclosed polypeptide that is required in order to obtain the functional and structural data needed to permit one to produce a polypeptide which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

Claim Rejections - 35 USC § 112, first paragraph

3. Claims 3-7, 9-10, 12-13, 46, 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 3, 12-13 are genus claims because they each recite “90% identical”, to the amino acid sequence of SEQ ID NO:1 or “90% identical” to SEQ ID NO:2 which terms encompasses variants of the polynucleotide encoding MCPP. The term variant means a protein having one or more amino acid substitutions, deletions, insertions and/or additions made to the protein molecule

of amino acid sequence set forth in SEQ ID NO:1 (see page 4, lines 22-32). The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the nucleic acid molecule. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art, the specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a nucleic acid encoding a protein set forth in SEQ ID NO:1 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus of protein molecules.

Therefore only an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:1, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. As a result, it does not appear that the

inventors were in possession of variants of a polynucleotide encoding a polypeptide of SEQ ID NO:1.

With respect to the limitation "an immunogenic fragment .....of SEQ ID NO:1" in claim 3, as recited, the claims broadly encompass all "epitope" portions of SEQ ID NO:1. The specification is only enabling for a polynucleotide encoding a polypeptide comprising SEQ ID NO:1 but is non-enabling for the full scope of the embodiments claimed. The term "immunogenic fragment" of the instant invention has not been described in the specification. Therefore, in the absence of delimiting amino acid sequences that make up the domain(s) or the epitopes of the instant MCPP polypeptide encoded by the claimed polynucleotide, a person of ordinary skill in the art would be unable to make domains or epitopes of the polypeptide, without undue experimentation. For this reason it would require undue experimentation to determine which are the immunogenic fragments of the MCPP polypeptide encoded by the claimed polynucleotide, a requisite property for the practice of the invention commensurate in scope with the claims.

Claims 4-7, 9-10, 46, 57 are rejected under 35 USC § 112, first paragraph insofar as they depend on claims 3, 12-13 for their limitations.

Claim rejections-35 USC § 112, second paragraph

4. Claims 3-7, 9-10, 46, 57 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rejected as vague and indefinite for several reasons.

Claim 3 recites has "chemotactic activity". However, it is unclear as to which type of cells the protein is chemotactic.

Furthermore, claim 3 recites "immunogenic fragment" which can encompass any six amino acids or the entire protein. The metes and bounds of this limitation are unclear.

Claims 4-7, 9-10, 46, 57 are rejected under 35 USC § 112, first paragraph insofar as they depend on claims 3, for their limitations.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Rollins et al. (US Patent No. 5,278,287) .

Rollins et al teach a the amino acid sequence of MCP-2/human JE factor and the polynucleotide encoding this protein (Table I and claims 1-2). A comparison of hJE protein and the instant MCPP polypeptide is set forth in Figure 2 of the instant application (GI-288397, SEQ ID NO:4). Therefore, the 10 consecutive amino acid peptides of hJE that are in common with MCPP of the instant invention comprise an immunogenic fragment of the amino acid sequence of SEQ ID NO:1 as in the present invention. The reference also discloses that the cDNA encoding hJE was cloned into a eukaryotic expression vector, pXM, which contains a promoter operably linked to the cDNA insert encoding the hJE protein, as shown by the ability of the vector to be

expressing hJE protein (Example I, columns 7-8, lines 6-30). Host cells, COS-1 cells were transformed with the cDNA in the vector (Example I, lines 24-30). Therefore, the polynucleotide disclosed in the reference meets the limitations of a polynucleotide of instant claims 3, 6-9 of the instant invention.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
February 24, 2003